IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

EAGLE PHARMACEUTICALS, INC. and EAGLE SUB1 LLC Plaintiffs, v. SLAYBACK PHARMA LLC and AZURITY PHARMACEUTICALS, INC. Defendants.	C.A. No. 25-75-JLH **JURY TRIAL DEMANDED**

SLAYBACK PHARMA LLC AND AZURITY PHARMACEUTICALS, INC.'S
RESPONSE TO SECOND AMENDED COMPLAINT

Slayback Pharma LLC ("Slayback") and Azurity Pharmaceuticals, Inc. ("Azurity") (collectively "Defendants") respond to Plaintiffs Eagle Pharmaceuticals, Inc. and Eagle Sub1 LLC (collectively "Eagle" or "Plaintiffs") Second Amended Complaint as follows:

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, to enjoin, and obtain damages resulting from, Slayback Pharma LLC ("Slayback") and Azurity Pharmaceuticals, Inc.'s ("Azurity") (collectively "Defendants") unauthorized importation into the United States, and use, sale, and/or offer for sale of products in the United States, that infringe at least one claim of Eagle's United States Patent Nos. 11,844,783 (the "'248 patent") and 11,872,214 (the "'248 patent") (collectively, the "Patent-in-Suit").

ANSWER:

Defendants admit that Plaintiffs' Second Amended Complaint states that this is an action for patent infringement under the patent laws of the United States, Title 35, United States Code that arises out of Defendants' importation into the United States, and use, sale, and/or offer for sale of Defendants' Bendamustine Hydrochloride Injection product ("Defendants' Product") prior to the expiration of Eagle's U.S. Patent No. 12,138,248 (the "'248 patent"). Defendants deny that Plaintiffs are entitled to any relief, including but not limited to the pled injunction or damages. Defendants deny all remaining allegations in paragraph 1.

2. Slayback submitted New Drug Application ("NDA") No. 212209 to the United States Food and Drug Administration ("FDA"), seeking approval to manufacture and sell a product that relies on data from bioavailability and/or bioequivalence studies contained in the Approved Labeling for Eagle's BELRAPZO®, 100 mg/4 mL (25 mg/mL) Bendamustine Hydrochloride Injection product, prior to the expiration of the Patent-in-Suit.

ANSWER:

Slayback denies the allegations of paragraph 2.

3. On information and belief, the FDA granted approval of NDA No. 212209 on December 7, 2022. Following said approval, Slayback began to import into the United States, and/or use, sell, and/or offer to sell in the United States, its NDA Product, VIVIMUSTA® (bendamustine hydrochloride injection) 100 mg/4 mL (25 mg/mL) (the "Azurity NDA Product"), along with the Approved Labeling for the same.

ANSWER:

Slayback admits that it received approval on or about December 7, 2022. Slayback admits that it later began to offer for sale and sell the currently marketed version of the VIVIMUSTA® product in the United States. Slayback denies that it later began to "use" the currently marketed version of the VIVIMUSTA® product in the United States. Slayback denies the remaining allegations of Paragraph 3.

4. On information and belief, Slayback was acquired by Azurity after the filing of the Complaint.

ANSWER:

Defendants deny the allegations of paragraph 4.

5. On information and belief, at some time after the filing of the Complaint, Azurity became the NDA holder for NDA No. 212209.

ANSWER:

Defendants deny the allegations of paragraph 5.

6. On information and belief, Azurity is the current NDA hold for NDA No. 212209. *See* https://www.accessdata.fda.gov/scripts/cder/ob/results_product.cfm?Appl_Type=N&Appl_No=212209#42297 (last visited June 6, 2025).

ANSWER:

Azurity admits that it is the current NDA holder for NDA No. 212209.

7. On information and belief, Azurity continues to import into the United States, and/or use, sell, and/or offer to sell in the United States, the Azurity NDA Product, VIVIMUSTA® (bendamustine hydrochloride injection) 100 mg/4 mL (25 mg/mL), along with the Approved Labeling for the same.

ANSWER:

Azurity admits that it sells and/or offers to sell the currently marketed version of the VIVIMUSTA® product in the United States. Azurity denies that it "continues to … use …VIVIMUSTA®" in the United States. Azurity denies the remaining allegations of paragraph 7.

PARTIES

8. Plaintiff Eagle Pharmaceuticals, Inc. is a corporation organized and existing under the laws of Delaware, with its corporate offices and principal place of business at 50 Tice Boulevard, Suite 315, Woodcliff Lake, New Jersey 07677.

ANSWER:

On information and belief, Defendants admit that Plaintiff Eagle Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Delaware, having corporate offices at 50 Tice Boulevard, Suite 315, Woodcliff Lake, New Jersey 07677. Defendants are without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 8 of the Second Amended Complaint and therefore deny same.

9. Plaintiff Eagle Sub1 LLC is a limited liability company organized and existing under the laws of Delaware, with its corporate offices and principal place of business at 50 Tice Boulevard, Suite 315, Woodcliff Lake, New Jersey 07677. Eagle Sub1 LLC is a wholly owned subsidiary of Eagle Pharmaceuticals, Inc.

ANSWER:

On information and belief, Defendants admit that Plaintiff Eagle Sub1 LLC is a limited liability company organized and existing under the laws of Delaware, having corporate offices at 50 Tice Boulevard, Suite 315, Woodcliff Lake, New Jersey 07677. On information and belief, Defendants admit that Eagle Sub1 LLC is a wholly owned subsidiary of Eagle Pharmaceuticals, Inc. Defendants are without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 9 of the Second Amended Complaint and therefore deny same.

10. On information and belief, Defendant Slayback is a company organized and existing under the laws of Delaware, with its principal place of business at 301 Carnegie Center, #303, Princeton, New Jersey 08540.

ANSWER:

Slayback admits that it is a company organized and existing under the laws of Delaware. Slayback denies that its principal place of business is at the stated address.

11. On information and belief, Slayback is a wholly-owned subsidiary of Azurity.

ANSWER:

Defendants admit that Slayback is a wholly-owned subsidiary of Azurity.

12. On information and belief, Defendant Azurity is a company organized and existing under the laws of Delaware, with its principal place of business at 8 Cabot Road, Suite 2000 Woburn, MA 01801.

ANSWER:

Azurity admits that it is a company organized and existing under the laws of Delaware. Azurity admits that its principal place of business is at the stated address.

13. On information and belief, Azurity is a generic pharmaceutical company that develops and manufactures generic versions of branded pharmaceutical products that it markets and distributes throughout the United States in concert with its subsidiary, Slayback.

ANSWER:

Paragraph 13 contains conclusions of law to which no response is required. To the extent a response is required, Defendants deny the allegations of paragraph 13.

14. On information and belief, Slayback and Azurity act in concert to import the Azurity NDA Product into the United States for sale, offer for sale, and use.

ANSWER:

Paragraph 14 contains conclusions of law to which no response is required. To the extent a response is required, Defendants deny the allegations of paragraph 14.

15. On information and belief, Slayback and Azurity are agents of each other, and/or operate in concert as integrated part of the same business group, and enter into agreements with each other that are nearer than arm's length, including with respect to the development, regulatory approval, marketing, sale, offer for sale, and distribution of pharmaceutical products throughout the United States, including in Delaware, and including with respect to the Azurity NDA Product.

ANSWER:

Paragraph 15 contains conclusions of law to which no response is required. To the extent a response is required, Defendants deny the allegations of paragraph 15.

16. The Approved Labeling for VIVIMUSTA® recites that it is "Manufactured at: Latina Pharma S.p.A. 04013 Sermoneta (LT), Italy" and "Manufactured for: Slayback Pharma LLC Princeton, NJ 08540." Approved Labeling for VIVIMUSTA®, (the "Approved Labeling"), available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/212209s005lbl.pdf (last visited June 6, 2025) at 22. On information and belief, Slayback directly or indirectly markets, sells, and distributes VIVIMUSTA® throughout the United States, including in Delaware.

ANSWER:

Paragraph 16 contains conclusions of law to which no response is required. To the extent a response is required, Slayback admits that its approved labeling includes the recited language. Slayback admits that the currently marketed version of the VIVIMUSTA® product is available in multiple states in the United States. Slayback denies all remaining allegations in paragraph 16.

17. On information and belief, following FDA approval of NDA No. 212209 and the acquisition of Slayback by Azurity, Slayback and Azurity acted and continue to act, in concert to market, distribute, offer for sale, and sell the Azurity NDA Product throughout the United States and within Delaware.

ANSWER:

Paragraph 17 contains conclusions of law to which no response is required. To the extent a response is required, Defendants deny the allegations of paragraph 17.

JURISDICTION AND VENUE

18. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

ANSWER:

Paragraph 18 contains conclusions of law to which no response is required. To the extent a response is required, Defendants admit that this Court has subject matter jurisdiction solely for the limited purposes of this particular action.

19. Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b), at least because Slayback and Azurity are incorporated in Delaware and therefore reside there for purposes of venue.

ANSWER:

Paragraph 19 contains conclusions of law to which no response is required. To the extent a response is required, Defendants deny that venue is appropriate under 28 U.S.C. § 1391, but does not contest venue solely for the limited purposes of this particular action.

20. Based on the facts and causes alleged herein, and for additional reasons to be further developed through discovery if necessary, this Court has personal jurisdiction over Slayback and Azurity.

ANSWER:

Paragraph 20 contains conclusions of law to which no response is required. To the extent a response is required, Defendants do not contest personal jurisdiction solely for the limited purposes of this particular action.

21. This Court has personal jurisdiction over Slayback because, on information and belief, Slayback is a company organized and existing under the laws of Delaware and maintains a registered agent for service of process in Delaware, at 1209 Orange Street, Wilmington, Delaware, 19801. This Court has personal jurisdiction over Slayback for the additional reasons set forth below and for other reasons that will be presented to the Court if such jurisdiction is challenged.

ANSWER:

Paragraph 21 contains conclusions of law to which no response is required. To the extent a response is required, Slayback does not contest personal jurisdiction solely for the limited purposes of this particular action.

22. This Court has personal jurisdiction over Azurity because, on information and belief, Azurity is a company organized and existing under the laws of Delaware and maintains a registered agent for service of process in Delaware, at 1209 Orange Street, Wilmington, Delaware, 19801. This Court has personal jurisdiction over Azurity for the additional reasons set forth below and for other reasons that will be presented to the Court if such jurisdiction is challenged.

ANSWER:

Paragraph 22 contains conclusions of law to which no response is required. To the extent a response is required, Azurity does not contest personal jurisdiction solely for the limited purposes of this particular action.

23. In addition, this Court has personal jurisdiction over Slayback and Azurity because, on information and belief, Slayback and Azurity have engaged in a persistent course of conduct within Delaware by continuously and systematically placing goods into the stream of commerce for distribution throughout the United States, including Delaware.

ANSWER:

Defendants deny the allegations of paragraph 23, but does not contest personal jurisdiction solely for the limited purposes of this particular action.

24. Further, this Court also has personal jurisdiction over Slayback and Azurity because, among other things, on information and belief: (1) Slayback filed NDA No. 212209 for the purpose of seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the product described in NDA No. 212209 in the United States, including in Delaware; (2) Azurity acquired Slayback and became the NDA Holder for NDA No. 212209; and (3) since NDA No. 212209 was approved, the product described in NDA No. 212209, VIVIMUSTA®, has been and continues to be imported, marketed, distributed, offered for sale, and/or sold in the United States, including in Delaware.

ANSWER:

Defendants admit that Slayback had filed NDA No. 212209 in the United States for the purposes described in NDA No. 212209 in the United States, that Azurity acquired Slayback and became the NDA Holder for NDA No. 212209, and that following approval Slayback launched the currently marketed version of the VIVIMUSTA® product which has been offered for sale and sold that product in multiple states in the United States. The remaining allegations of paragraph 24 contain conclusions of law as to which no response is required. To the extent a response is required, Defendants does not contest personal jurisdiction solely for the limited purposes of this particular action. Defendants deny the remaining allegations of paragraph 24.

25. The Court also has personal jurisdiction over Slayback and Azurity because they have committed, aided, abetted, induced, contributed to, or participated in the commission of the tortious act of patent infringement that has harmed and injured Eagle, which is a Delaware corporation.

ANSWER:

Defendants admit that Eagle is a Delaware corporation. Defendants do not contest personal jurisdiction solely for the limited purposes of this particular action. Defendants deny all other allegations of paragraph 25.

26. Slayback has previously consented to jurisdiction in Delaware in many prior cases arising out of the filing of its drug applications, including the application for the product at issue in this litigation, and it has asserted counterclaims in such cases. *See, e.g.*, *Cephalon, Inc. & Eagle Pharm., Inc. v. Slayback Pharma LLC*, No. 17-1154-CFC, D.I. 11 (D. Del. Sep. 29, 2017); *Teva Pharma. Int'l GmbH, Cephalon, Inc. & Eagle Pharma., Inc. v. Slayback Pharma LLC*, No. 18-117-CFC, D.I. 9 (D. Del. Feb. 12, 2018); *Eagle Pharm., Inc. v. Slayback Pharma LLC*, No. 18-1459-CFC, D.I. 9 (D. Del. Oct. 10, 2018); *Eagle Pharm., Inc. v. Slayback Pharma LLC*, No. 18-1953-CFC, D.I. 12 (D. Del. Jan. 3, 2019); *Eagle Pharm. Inc. v. Slayback Pharma LLC*, No. 21-1256-CFC, D.I. 9 (D. Del. Sept. 22, 2021).

ANSWER:

Slayback admits that it did not contest personal jurisdiction solely for the limited purposes of the particular identified actions and that it asserted counterclaims in certain of the identified cases.

27. Azurity has previously consented to jurisdiction in Delaware in many prior cases, arising out of its manufacture, use, offer for sale, sale and/or importation of pharmaceutical products, including cases that it initiated as plaintiff. *See, e.g.*, *Azurity Pharms., Inc. v. Hetero Laby's Ltd.*, C.A. No. 24-396-MN, D.I. 1 (D. Del. Mar. 28, 2024); *Azurity Pharms., Inc. v. Zydus Pharms (USA) Inc.*, C.A. No. 23-833-MN, D.I. 1 (D. Del. Aug. 2, 2023); *Azurity Pharms., Inc. v. Teva Pharms., Inc.*, C.A. No. 23-1080-MN, D.I. 1 (D. Del. Sept. 29, 2023); *Azurity Pharms., Inc. v. Accord Healthcare, Inc.*, C.A. No. 23-373-CFC, D.I. 1 (D. Del. Mar. 31, 2023); *Azurity Pharms., Inc. v. Novitium Pharma, LLC*, C.A. No. 23-163-MSG, D.I. 1 (D. Del. Feb. 14, 2023); *Azurity Pharms., Inc. v. Glenmark Pharms., Inc.*, C.A. No. 22-1604-MN, D.I. 1 (D. Del. Dec. 16, 2022); *Azurity Pharms., Inc. v. Aurobindo Pharma Ltd.*, C.A. No. 21-1707-MSG, D.I. 1 (D. Del. Dec. 2, 2021); *Azurity Pharms., Inc. v. CoreRx, Inc.*, C.A. No. 21-1522-LPS, D.I. 1 (D. Del. Oct. 27, 2021); *Azurity Pharms., Inc. v. Bionpharma Inc.*, C.A. No. 21-1455-MSG, D.I. 1 (D. Del. Oct. 15, 2021); *Heron Therapeutics, Inc. v. Azurity Pharms., Inc.*, C.A. No. 24-1363-WCB, D.I. 22 (D. Del. Jan. 10, 2025).

ANSWER:

Azurity admits that it did not contest personal jurisdiction solely for the limited purposes of the particular identified actions and that it asserted counterclaims in certain of the identified cases.

28. For at least the above reasons, it would not be unfair or unreasonable for Slayback and Azurity to litigate this action in this District, and there is personal jurisdiction over Slayback and Azurity for purposes of this action.

ANSWER:

Paragraph 28 contains conclusions of law to which no response is required. To the extent a response is required, Defendants do not contest personal jurisdiction solely for the limited purposes of this particular action. Defendants deny all other allegations of paragraph 28.

BACKGROUND

29. BELRAPZO®, which contains bendamustine hydrochloride, is an alkylating drug that is indicated for the treatment of patients with chronic lymphocytic leukemia, as well as for the treatment of patients with indolent B-cell non-Hodgkin lymphoma that has progressed during or within six months of treatment with rituximab or a rituximab-containing regimen.

ANSWER:

Upon information and belief, Defendants admit that BELRAPZO® contains bendamustine hydrochloride. Upon information and belief, Defendants admit that the prescribing information for BELRAPZO® provides that BELRAPZO® is "an alkylating drug indicated for treatment of patients with: Chronic lymphocytic leukemia (CLL)" and "Indolent B-cell non-Hodgkin Lymphoma (NHL) that has progressed during or within six months of treatment with rituximab or a rituximab-containing regimen." Defendants deny all remaining allegations in paragraph 29.

30. Eagle Pharmaceuticals, Inc. is the holder of NDA No. 205580 for BELRAPZO®, which has been approved by the FDA.

ANSWER:

Upon information and belief, Defendants admit that Eagle Pharmaceuticals Inc. is the holder of NDA 205580 for BELRAPZO®. Upon information and belief, the FDA approved NDA No. 205580.

31. The '248 patent, entitled "Formulations of Bendamustine" (Exhibit A hereto), was duly and legally issued on November 12, 2024. Eagle Sub1 LLC is the owner and assignee of the '248 patent. Eagle Pharmaceuticals, Inc. has an exclusive license to the '248 patent to develop, manufacture, use, offer to sell, sell, promote, distribute, export and import, enforce, and otherwise exploit the '248 patent with respect to BELRAPZO®.

ANSWER:

Defendants admit that the '248 patent is entitled "Formulations of Bendamustine" and that the '248 patent states on its face that it was issued on November 12, 2024. Defendants also admit that what is purported to be a copy of the '248 patent is attached to the Second Amended Complaint as Exhibit A. Defendants deny that the '248 patent is valid and enforceable. Defendants are without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 31 of the Second Amended Complaint and therefore deny same. Defendants deny any other allegations of paragraph 31.

32. Eagle Pharmaceuticals, Inc. timely submitted the '248 patent to be listed in connection with BELRAPZO® in the FDA's publication *Approved Drug Products with Therapeutic Equivalence Evaluations*, also known as the "Orange Book."

ANSWER:

On information and belief, Defendants admit that the '248 patent is listed in connection with BELRAPZO® in the FDA's publication "Approved Drug Products with Therapeutic Equivalence Evaluations," also known as the "Orange Book," but Defendants deny that the listing is appropriate. Defendants deny any other allegations of paragraph 32.

33. Claim 1 of the '248 patent recites:

> A sterile container containing a liquid bendamustine-containing composition comprising
>
> bendamustine, or a pharmaceutically acceptable salt thereof, wherein the bendamustine concentration in the composition is about 25 mg/mL;
>
> a pharmaceutically acceptable fluid consisting of polyethylene glycol and optionally one or more of propylene glycol, ethanol, benzyl alcohol and glycofurol; and
>
> a stabilizing amount of an antioxidant,
>
> wherein the total impurities resulting from the degradation of the bendamustine is less than about 5% peak area response, as determined by HPLC at a wavelength of 223 nm after at least about 15 months at a temperature of about 5 °C to about 25 °C.

ANSWER:

Admitted.

34. BELRAPZO® is a product that falls within the ambit of at least claim 1 of the '248 patent.

ANSWER:

Denied.

35. The '248 patent is also listed in the Orange Book for the drug product BENDEKA®, which is marketed by Teva Pharmaceuticals ("Teva") under a license from Eagle to Teva. BENDEKA® likewise is a drug product that falls within the ambit of at least claim 1 of the '248 patent.

ANSWER:

On information and belief, Defendants admit that the '248 patent is listed in connection with BENDEKA® in the Orange Book, but Defendants deny that the listing is appropriate. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding Teva in paragraph 35 of the Second Amended Complaint and therefore denies same. Paragraph 35 contains conclusions of law regarding BENDEKA® to which no response is required. To the extent a response is required, Defendants deny any other allegations of paragraph 35.

INFRINGEMENT BY DEFENDANTS

36. On information and belief, the Azurity NDA Product, marketed and sold as VIVIMUSTA®, received final approval from the FDA on December 7, 2022. *See* Drugs@FDA, Vivimusta, https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process &ApplNo=212209 (last visited June 6, 2025).

ANSWER:

Slayback admits that it received approval on or about December 7, 2022. Slayback admits that it later began to offer for sale and sell the currently marketed version of the VIVIMUSTA® product. Slayback denies the remaining allegations of Paragraph 36.

37. On information and belief, since the approval of VIVIMUSTA®, Defendants have been importing VIVIMUSTA® into the United States, using VIVIMUSTA® in the United States, offering VIVIMUSTA® for sale in the United States, and selling VIVIMUSTA® in the United States. VIVIMUSTA® is prominently listed as a product for sale by Defendants on their website. *See* https://vivimusta.com (last visited June 6, 2025).

ANSWER:

Slayback admits that it has offered for sale, and sold the currently marketed version of the VIVIMUSTA® product in the United States. Azurity admits that it has offered for sale and sold the currently marketed version of the VIVIMUSTA® product in the United States. Defendants deny that they have been "using VIVIMUSTA® in the United States." Defendants deny the remaining allegations of paragraph 37.

38. On information and belief, since Azurity acquired Slayback and became the NDA holder for NDA No. 212209, Azurity has become responsible for advertising, marketing, promoting, offering for sale, selling and/or importing the Azurity NDA Product, VIVIMUSTA®, in the United States. *See* https://azurity.com/azurity-pharmaceuticals-acquires-slayback-pharma (last visited June 6, 2025).

ANSWER:

Paragraph 38 contains conclusions of law to which no response is required. To the extent a response is required, Azurity denies the allegations of paragraph 38.

39. Azurity's websites include promotional materials directed to the marketing, promotion, and sale of the Azurity NDA Product, VIVIMUSTA®, including the Approved Labeling.. See. e.g, https://azurity.com/products (last visited June 6, 2025); https://www.vivimustaconnect.com/doctor_cases/new (last visited June 6, 2025).

ANSWER:

Paragraph 39 contains conclusions of law to which no response is required. Defendants admit that the website https://vivimusta.com/ provides information regarding the currently marketed version of the VIVIMUSTA® product. Defendants deny all other allegations in paragraph 39 to the extent they are in contradiction to the statements contained on that website and denies all remaining allegations of paragraph 39.

40. On information and belief, VIVIMUSTA® relies on data from bioavailability and/or bioequivalence studies contained in the Approved Labeling for BELRAPZO®. BELRAPZO® is approved for a 24-month shelf life. The Approved Labeling for VIVIMUSTA® does not identify any difference in stability between VIVIMUSTA® and BELRAPZO® and, on information and belief, VIVIMUSTA® has the same or substantially similar stability as BELRAPZO® and/or as recited in the claims of the Patent-in-Suit.

ANSWER:

Defendants admit that the currently marketed version of the VIVIMUSTA® product has an approved labeling and refer Plaintiffs to that labeling for the content therein. Defendants deny the remaining allegations of paragraph 40.

41. Publicly-available materials from the FDA's review of Azurity's NDA No. 212209 indicate that "in the September 16, 2019 CRL, [Slayback] provided updated stability data for the finished product in support of the proposed 24-month expiry. Based on the information provided, Slayback

Pharma LLC. proposed and the FDA accepts the expiration dating period of **24 months** for the drug product when stored at [sic] between 2–8 °C." Product Quality Review(s), Application No. 212209Orig1s000, available at https://www.accessdata.fda.gov/drugsatfda_docs/nda/2023/212209Orig1s000ChemR.pdf (last visited June 6, 2025) (the "Product Quality Review") at p. 37. Thus, on information and belief, VIVIMUSTA®, as sold, used, or offered for sale in the United States, satisfies the stability limitations set forth in the claims of the Patent-in-Suit.

ANSWER:

Defendants admit that the document accessible at the identified URL relates to Defendants' NDA No. 212209 and refer Plaintiffs to that document for the content therein. The stability criteria for the currently marketed version of the VIVIMUSTA® product is set forth in NDA No. 212209. Defendants denies all remaining allegations of paragraph 41.

42. The Approved Labeling for VIVIMUSTA® states that the active ingredient is bendamustine hydrochloride. *See* Approved Labeling at 1; *see also Eagle Pharm., Inc. v. Slayback Pharma LLC*, 958 F.3d 1171, 1173 (Fed. Cir. 2020).

ANSWER:

Defendants admit that the currently marketed version of the VIVIMUSTA® product has an approved labeling and refer Plaintiffs to that labeling for the content therein.Defendants deny the remaining allegations of paragraph 42.

43. The Approved Labeling for VIVIMUSTA® states that the dosage strength is 25 mg/mL. *See id.*

ANSWER:

Defendants admit that the currently marketed version of the VIVIMUSTA® product has an approved labeling and refer Plaintiffs to that labeling for the content therein.

44. The Approved Labeling for VIVIMUSTA® states that it contains polyethylene glycol ("PEG"), which is described and claimed as a pharmaceutically acceptable fluid in the Patent-in-Suit. *See id.* at 15. The Approved Labeling for VIVIMUSTA® further states that it contains "absolute alcohol," which is a known, commercially available grade of ethanol, which is likewise described and claimed as a pharmaceutically acceptable fluid in the Patent-in-Suit. *See id.* Thus, Defendants' VIVIMUSTA® contains "a pharmaceutically acceptable fluid consisting of

polyethylene glycol and optionally . . . ethanol," consistent with claim 1 of each of the Patent-in-Suit.

ANSWER:

Defendants admit that the currently marketed version of the VIVIMUSTA® product has an approved labeling and refer Plaintiffs to that labeling for the content therein. Defendants deny the remaining allegations of paragraph 44.

45. The Approved Labeling for VIVIMUSTA® also recites that "[e]ach milliliter contains 25 mg of bendamustine hydrochloride equivalent to 22.7 mg of bendamustine, 5 mg of monothioglycerol, 39.45 mg (5% v/v) of absolute alcohol, and q.s. to 1 mL polyethylene glycol 400." *Id.* at 15. The Approved Labeling then states: "Sodium hydroxide is used to adjust [the] pH of polyethylene glycol 400." *Id.* Sodium hydroxide is not a pharmaceutically acceptable fluid as that term is used in the specification of the '248 patent, nor is it a component of the pharmaceutically acceptable fluid in VIVIMUSTA®. Thus, it is not pertinent to the "pharmaceutically acceptable fluid" limitation of claim 1 of each of the Patent-in-Suit.

ANSWER:

Defendants admit that the currently marketed version of the VIVIMUSTA® product has an approved labeling and refer Plaintiffs to that labeling for the content therein. Defendants deny the remaining allegations of paragraph 45.

46. Indeed, in referring to the use of sodium hydroxide, the Approved Labeling does not describe sodium hydroxide as a component of VIVIMUSTA®, but rather notes that "sodium hydroxide is used to adjust [the] pH ***of polyethylene glycol 400***" used to manufacture VIVIMUSTA®. *Id.* at 15. Thus, that fluid remains "***polyethylene glycol 400***" and is not taken outside the confines of being a "pharmaceutically acceptable fluid" by any use of sodium hydroxide during its preparation.

ANSWER:

Defendants admit that the currently marketed version of the VIVIMUSTA® product has an approved labeling and refer Plaintiffs to that labeling for the content therein. Defendants deny the remaining allegations of paragraph 46.

47. The Approved Labeling notes that VIVIMUSTA® is "Manufactured at: Latina Pharma S.p.A." in "Sermoneta (LT), Italy." *Id.* at 22. In certain instances, on information and belief, Defendants' Italian manufacturer uses sodium hydroxide in batches of PEG. In those instances,

any addition of sodium hydroxide to the PEG during manufacturing in Italy is for the purposes of ensuring that VIVIMUSTA® has a pharmaceutically acceptable fluid as part of its liquid bendamustine-containing formulation at the time of importation, offer for sale, use, and/or sale of same in the United States.

ANSWER:

Defendants admit that the currently marketed version of the VIVIMUSTA® product has an approved labeling and refer Plaintiffs to that labeling for the content therein. Defendants deny the remaining allegations of paragraph 47.

48. Publicly-available materials from the FDA's review of Azurity's NDA No. 212209 indicate that sodium hydroxide is only used in a "quantity sufficient" to "adjust [the] pH of polyethylene glycol 400." Product Quality Review at p. 6, 67.

ANSWER:

The referenced document "Product Quality Review" is not sufficiently identified to determine the accuracy of the alleged quotation and therefore Defendants deny the allegations of paragraph 48.

49. The Approved Labeling similarly does not list a specific amount of sodium hydroxide or indicate that it is necessary in all instances. Rather, the Approved Labeling for VIVIMUSTA® recites that "[e]ach milliliter contains 25 mg of bendamustine hydrochloride equivalent to 22.7 mg of bendamustine, 5 mg of monothioglycerol, 39.45 mg (5% v/v) of absolute alcohol, and q.s. to 1 mL polyethylene glycol 400." *Id.* at 15. Therefore, on information and belief, while the Approved Labeling states that "[s]odium hydroxide is used to adjust [the] pH of polyethylene glycol 400" in VIVIMUSTA® (Approved Labeling at 15), sodium hydroxide is not used for each batch of the PEG used in the manufacture of VIVIMUSTA®.

ANSWER:

Defendants admit that the currently marketed version of the VIVIMUSTA® product has an approved labeling and refer Plaintiffs to that labeling for the content therein. Defendants deny the remaining allegations of paragraph 49.

50. Even in an instance where sodium hydroxide is used to adjust the pH of batches of PEG used to manufacture VIVIMUSTA®, on information and belief, sodium hydroxide is not a component of the product that is imported into the United States, sold and/or offered for sale in the United States, and/or used in the United States. Thus, the Approved Labeling for VIVIMUSTA® recites that "[e]ach milliliter contains 25 mg of bendamustine hydrochloride equivalent to 22.7 mg

of bendamustine, 5 mg of monothioglycerol, 39.45 mg (5% v/v) of absolute alcohol, and q.s. to 1 mL polyethylene glycol 400." *Id.* at 15. As explained on Defendants' Approved Labeling, sodium hydroxide is used as a pH adjuster and, on information and belief, is consumed by such use and/or is otherwise not a component of VIVIMUSTA®.

ANSWER:

Defendants admit that the currently marketed version of the VIVIMUSTA® product has an approved labeling and refer Plaintiffs to that labeling for the content therein. Defendants deny the remaining allegations of paragraph 50.

51. Additionally, the use of sodium hydroxide is well known to those of skill in the art to adjust the pH of both pharmaceutical formulations generally, and of PEG specifically. Sodium Hydroxide, National Library of Medicine, https://pubchem.ncbi.nlm.nih.gov/compound/Sodium-Hydroxide, (last visited June 6, 2025). Thus, even if Defendants' Italian manufacturer uses sodium hydroxide to adjust the pH of PEG in the manufacturing process, a person of ordinary skill in the art would not consider any such use to take VIVIMUSTA® outside the scope of the claim element "a pharmaceutically acceptable fluid consisting of polyethylene glycol and optionally one or more of propylene glycol, ethanol, benzyl alcohol and glycofurol." *See, e.g.,* '248 patent at claim 1. Further, by time of importation, offer for sale, use, and/or sale, VIVIMUSTA® has a pharmaceutically acceptable fluid as part of its liquid bendamustine-containing formulation given that Defendants promote that it is pharmaceutically acceptable for administration to humans. "VIVIMUSTA is an alkylating drug indicated for the treatment of adult patients . . ." https://vivimusta.com/ (last visited June 6, 2025).

ANSWER:

Denied.

52. The Approved Labeling for VIVIMUSTA® also recites that "[e]ach milliliter contains 25 mg of bendamustine hydrochloride [and] . . . 5 mg of monothioglycerol." Approved Labeling at 15. The shared specification for the Patent-in-Suit indicates that monothioglycerol is an antioxidant and that 5 mg/mL is a stabilizing amount of an antioxidant.

ANSWER:

Defendants admit that the currently marketed version of the VIVIMUSTA® product has an approved labeling and refer Plaintiffs to that labeling for the content therein. Defendants deny the remaining allegations of paragraph 52.

53. On information and belief, VIVIMUSTA® has less than about 5% peak area response of total impurities resulting from the degradation of the bendamustine, as determined by HPLC at a

wavelength of 223 nm after at least 15 months at a temperature of from about 5 °C to about 25 °C. Further, Defendants have conceded that VIVIMUSTA® meets an identical limitation in U.S. Patent No. 9,572,796, which is related to the Patent-in-Suit and shares a specification with them. *Eagle Pharmaceuticals Inc. v. Slayback Pharma LLC*, 958 F.3d 1171, 1173 (Fed. Cir. 2020).

ANSWER:

Defendants refer Plaintiffs to the published decision *Eagle Pharmaceuticals Inc. v. Slayback Pharma LLC*, 958 F.3d 1171 (Fed. Cir. 2020) for the content therein. Defendants deny the remaining allegations of paragraph 53.

54. The Approved Labeling for VIVIMUSTA® encourages, recommends, instructs, and/or promotes administration to patients with chronic lymphocytic leukemia. *See* Approved Labeling.

ANSWER:

Defendants admit that the currently marketed version of the VIVIMUSTA® product has an approved labeling and refer Plaintiffs to that labeling for the content therein. Defendants deny the remaining allegations of paragraph 54.

COUNT I – INFRINGEMENT OF U.S. PATENT NO. 12,138,248

55. Eagle incorporates each of the preceding paragraphs as if fully set forth herein.

ANSWER:

Defendants incorporate by reference their responses to paragraphs 1-54 as if fully set forth herein.

56. As set forth herein, Defendants have offered VIVIMUSTA® for sale in the United States, sold VIVIMUSTA® in the United States, used VIVIMUSTA® in the United States, and/or imported VIVIMUSTA® into the United States.

ANSWER:

Defendants deny that they have "used VIVIMUSTA® in the United States." Defendants admit the remaining allegations of paragraph 56 with regard to the currently marketed version of the VIVIMUSTA® product.

57. On information and belief, the importation, manufacture, sale, offer for sale, and/or use of VIVIMUSTA® in conjunction with its Approved Labeling infringes one or more claims, including at least claim 1, of the '248 patent under 35 U.S.C. § 271(a), either literally and/or under the doctrine of equivalents, and/or Defendants induce or contribute to the inducement of the infringement of one or more claims, including at least claim 1, of the '248 patent under 35 U.S.C. § 271(b) and/or (c).

ANSWER:

Defendants deny the allegations of paragraph 57.

58. As reflected in its Approved Labeling, each milliliter of VIVIMUSTA® "contains 25 mg of bendamustine hydrochloride equivalent to 22.7 mg of bendamustine, 5 mg of monothioglycerol, 39.45 mg (5% v/v) absolute alcohol, and q.s. to 1 mL polyethylene glycol 400." Approved Labeling at 15. That Approved Labeling further indicates that VIVIMUSTA® is marketed in a 100 mg/4 mL vial. *Id.* at 20.

ANSWER:

Defendants admit that the currently marketed version of the VIVIMUSTA® product has an approved labeling and refer Plaintiffs to that labeling for the content therein. Defendants deny that the list contained in paragraph 58 is the full list of ingredients in the currently marketed version of the VIVIMUSTA® product. Defendants deny all allegations in paragraph 58 to the extent they are in contradiction to the statements contained in the referenced document and denies all remaining allegations of paragraph 58.

59. The foregoing actions by Defendants constitute infringement of the '248 patent, active inducement of infringement of the '248 patent, and contribution to the infringement by others of the '248 patent.

ANSWER:

Defendants deny the allegations of paragraph 59.

60. Defendants' infringement and/or inducement is willful. On information and belief, Defendants are aware of the '248 patent at least because Slayback is aware of Eagle's patent portfolio and has previously been involved in litigation concerning other patents related to the '248 patent. *See, e.g.*, *Eagle Pharm. Inc. v. Slayback Pharma LLC*, No. 21-1256-CFC, D.I. 9 (D. Del. Sept. 22, 2021). Further, Defendants have been aware of the '248 patent and their related infringement at least since Eagle Pharmaceuticals, Inc. sent a letter to Slayback dated January 16, 2024, informing Slayback that the '248 patent had issued and the importation, sale, offer for sale,

and/or use of VIVIMUSTA® in conjunction with its Approved Labeling infringed the '248 patent. Moreover, on information and belief, Defendants have regularly monitored Eagle's patent filings and developments in the '248 patent family.

ANSWER:

Defendants deny the allegations of paragraph 60.

61. On information and belief, Defendants have acted with full knowledge of the '248 patent and/or the application leading to the '248 patent, Application No. 18/081,251, and without a reasonable basis for believing that it would not be liable for infringing the '248 patent, actively inducing infringement of the '248 patent, and contributing to the infringement by others of the '248 patent.

ANSWER:

Defendants deny the allegations of paragraph 61.

62. Unless Defendants are enjoined from infringing the '248 patent, actively inducing infringement of the '248 patent, and contributing to the infringement by others of the '248 patent, Eagle will suffer irreparable injury. Eagle has no adequate remedy at law.

ANSWER:

Defendants deny the allegations of paragraph 62.

63. Eagle has suffered monetary damages, including but not limited to lost profits, as a result of Defendants' infringement of the '248 patent.

ANSWER:

Defendants deny the allegations of paragraph 63.

JURY DEMAND

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Defendants hereby demand a trial by jury on all issues triable as such.

PRAYER FOR RELIEF

Defendants deny that Plaintiffs are entitled to any relief. Defendants respectfully request that the Court dismiss Plaintiffs' Second Amended Complaint with prejudice, enter judgment in

favor of Defendants, award Defendants their reasonable attorneys' fees and costs incurred in defending this suit, and award Defendants such other relief as the Court deems just and proper.

SEPARATE ADDITIONAL DEFENSES

Further answering the Second Amended Complaint, and as additional defenses thereto, Defendants assert the following separate defenses without prejudice to the denials in this Answer, without admitting any allegations of the Second Amended Complaint not otherwise admitted. Defendants assert these additional defenses without conceding that they bear a burden of proof on them and reserve the right to assert additional defenses as warranted.

First Separate Additional Defense

The claims of the Patent-in-Suit is invalid for failure to comply with one or more conditions of patentability set forth in one or more provisions of 35 U.S.C. § 101 *et seq.*, including 35 U.S.C. §§ 101, 102, 103, 112 and/or 116, double patenting, or under other judicially-created bases for invalidation or unenforceability.

Second Separate Additional Defense

Plaintiffs' Second Amended Complaint fails to state a claim upon which relief can be granted, and fails to state a claim for exceptional case. The Second Amended Complaint fails to provide the requisite detail to assert infringement, and does not provide a good faith basis for the claim that is being made.

Third Separate Additional Defense

Plaintiffs are not entitled to relief because they have not adequately pled, shown, nor proven adequate standing for the relief sought.

Fourth Separate Additional Defense

Plaintiffs' cause of action is barred, in whole or in part, by the doctrine of prosecution history estoppel and other doctrines that limit the application of the claims to the accused products. Plaintiffs are estopped from arguing and has waived arguments that its claims cover Defendants' Product by virtue of amendment, positions, and arguments made to the USPTO when obtaining the Patent-in-Suit.

Fifth Separate Additional Defense

Plaintiffs are not entitled to injunctive relief because they have not and cannot prove the required elements to obtain such relief, including that: (1) they have suffered irreparable injury; (2) there is no adequate remedy at law; (3) a remedy in equity is warranted; and (4) the public interest warrants an injunction.

Sixth Separate Additional Defense

The manufacture, use, importation, sale or offer for sale of the currently marketed version of the VIVIMUSTA® Product described in NDA No. 212209 has not infringed, contributed to the infringement of, or induced the infringement of any valid and/or enforceable claim of the Patent-in-Suit literally or under the doctrine of equivalents.

Seventh Separate Additional Defense

The claims of the Second Amended Complaint are barred, in whole or in part, by the prior judgment in *Eagle Pharms., Inc. v. Slayback Pharma LLC*, Civil Action No. 21-1256-CFC-JLH, 2022 U.S. Dist. LEXIS 193941 (D. Del. Oct. 25, 2022) by the doctrines of estoppel, waiver, issue preclusion, claim preclusion or the Kessler doctrine.

Reservation of Additional Defenses

Defendants reserve the right to assert additional defenses that may be developed through discovery, or otherwise, in this action.

Dated: July 3, 2024

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